K131401

JUL 0 2 2013

5. 510(K) SUMMARY

510(k) Applicant
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Date of Summary: 27 June 2013

Device Overview
Trade Name: Blowfish™ Transbronchial Micro-Infusion Catheter

Common Name: Transbronchial Catheter

Classification: Bronchoscope (flexible or rigid) and Accessories
21 CFR 874.4680
Product Code EOQ
Panel: ENT

Predicate Devices

510(k) Number	Product Name	Manufacturer
K962901	Olympus B5-2C/B7-2C Balloon Catheter	Olympus

Device Description
The Blowfish™ Transbronchial Micro-Infusion Catheter is a bronchoscope guided, single-operator, catheter that consists of a microscopic, tapered stainless steel infusion port, a semi-rigid/semi-elastic polymer balloon, a composite metal and polymer catheter shaft, a pressure relief valve and a proximal hub with standard luer attachment fittings. The device is designed to be advanced through a bronchoscope to a target location in the tracheobronchial three and inflated to move the micro-infusion port into the airway wall to deliver therapeutics to the bronchial tissue including the bronchial adventitia.

Intended Use
Bronchoscope accessories in the airway tree for medicine infusion.

Indications for Use

The Blowfish™ Transbronchial Micro-Infusion Catheter is intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or bronchial delivery into selected and sub-selected regions of the airway tree.

Comparison to Predicate Device

The Blowfish Transbronchial Micro-Infusion Catheter is substantially equivalent to the predicate. The Blowfish Transbronchial Micro-Infusion Catheter has the same intended use, methods of introduction and methods of operation. Risk analysis has shown that the Blowfish Transbronchial Micro-Infusion Catheter has the same risk profile as the predicate. The Indication for Use statement of the predicate is broader and includes selective endoscopic bronchography, medicine injection to bronchi, saline injection associated with bronchoalveolar lavage, foreign body removal from bronchi and bronchial hemostasis, while the Indication for Use statement for the Blowfish Transbronchial Micro-Infusion Catheter is only limited to the medicine injection portion of the predicate. By selecting a narrower Indication for Use statement compared to the predicate, Mercator believes that the differences in the wording are not critical and thus the requirement of 807.92(a)(5) is met.

Comparison of Key Technological Characteristics:

NAME / 510(K) NUMBER	**Blowfish Transbronchial Micro-Infusion Catheter** (Current Submission)	**Olympus B5-2C/B7-2C Balloon Catheter** / K962901
MANUFACTURER	Mercator MedSystems	Olympus
INTENDED USE	Bronchoscope accessories in the airway tree for medicine infusion.	Bronchoscope accessories in the airway tree for medicine infusion.
INDICATIONS FOR USE	The Blowfish™ Transbronchial Micro-Infusion Catheter is intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or bronchial delivery into selected and sub-selected regions of the airway tree.	Olympus B5-2C/B7-2C Balloon Catheters are to be used for selective endoscopic bronchography, medicine injection to bronchi, saline injection associated with bronchoalveolar lavage, foreign body removal from bronchi and bronchial hemostasis.
TARGETED LOCATION	Tracheobronchial Tree	Tracheobronchial Tree
INFUSION		
Delivery Method into the Bronchi	Infusion via a Stainless Steel Port	Infusion via Polymer Port
Number of Delivery Ports	One (on the side)	One (at the tip)
Delivery Port Size	34 Gauge	Unknown
ACTUATOR / BALLOON		
Material	Parylene and Silicone	Natural Rubber Latex
Target Diameter	6.0 mm to 16.0 mm	11 mm
Max Inflation Pressure	2 atm controlled by pressure relief valve	No pressure relief valve
Shape (cross-section)	U-shaped balloon sheathing micro-infusion port	O-shaped balloon surrounding infusion port
Inflation medium	Liquid	Air (max 2.1 mL)
CATHETER		
Material	Pebax	Unknown

NAME / 510(K) NUMBER	**Blowfish Transbronchial Micro-Infusion Catheter** (Current Submission)	**Olympus B5-2C/B7-2C Balloon Catheter** / K962901
Length	Up to 145 cm	105 cm
BRONCHOSCOPE CHANNEL ID	2.8 mm	2.0 – 2.8 mm
PACKAGING	Tyvek Pouch	Tyvek Pouch
STERILIZATION METHOD	E-beam	Ethylene Oxide
STERILITY	Sterile (SAL 10^{-6})	Sterile (SAL 10^{-6})
SINGLE USE	Yes	Yes
STORAGE	Room Temperature	Ambient temperature 10°C – 40°C (50°F – 104°F) Relative Humidity 30 – 85%

Performance Data

Device performance of the Blowfish Transbronchial Micro-Infusion Catheter was tested in bench, in vitro and in vivo animal studies. Performance testing was conducted to verify that it meets the mechanical performance requirements defined by the product specification after exposure to E-Beam irradiation, aging and simulated distribution. All tests met the pre-determined acceptance criteria.

The testing included the following:

- mechanical and fluid delivery performance
- packaging and labeling testing
- shelf-life testing
- biocompatibility per ISO 10993-1: cytotoxicity, sensitization, intracutanious reactivity and acute toxicity, was previously conducted with a legally marketed device (K062752)
- in-vivo safety studies using a porcine model

Conclusion

When compared to the predicate device, the Blowfish Transbronchial Micro-Infusion Catheter has the same intended use and target location. Test results indicated that the catheter's materials, mode of action and procedure (i.e. via a bronchoscope) are safe and do not raise different questions of safety and effectiveness compared to the predicate device (Olympus B5-2C/B7-2C Balloon Catheter, K962901). The materials included in the Blowfish Transbronchial Micro-Infusion Catheter were tested and demonstrated to be biocompatible and safe. The Blowfish Transbronchial Micro-Infusion Catheter labeling contains instructions for use and any necessary cautions and warnings to assure safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 2, 2013

Mercator MedSystems, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K131401
Trade/Device Name: Blowfish™ Transbronchial Micro-Infusion Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Transbronchial Catheter
Regulatory Class: Class II
Product Code: EOQ
Dated: May 14, 2013
Received: May 15, 2013

Dear Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number: K131401

Device Name: Blowfish™ Transbronchial Micro-Infusion Catheter

Indications For Use:

The Blowfish™ Transbronchial Micro-Infusion Catheter is intended to deliver therapeutic and diagnostic agents that are indicated or labeled for airway, tracheal or bronchial delivery into selected and sub-selected regions of the airway tree.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Eric A. Mann -S